acteristics were comparable between the two cohorts (all p-values>0.05). During median follow-up of 2.95 years, the cumulative incidence of death was 304 (17.72%) among 1716 PADT patients and 94 (5.48%) among 1716 RP patients; 66 (3.85%) and 2 (0.12%) for prostate cancer specific deaths, respectively. The PADT group had nearly 4 times higher overall mortality risk compared to those using RP (odds ratio (OR)=3.534, 95% confidence interval (CI)=2.801-4.464, p<0.001). Furthermore, patients who received PADT had significantly higher prostate cancer specific mortality compared to those using RP (OR=30.875, 95% CI=7.535-126.506, p<0.001). **CONCLUSIONS:** Overall mortality and prostate cancer specific mortality following PADT were significantly higher compared to those following RP among localized prostate cancer patients. These data do not support the use of PADT in men with clinically localized prostate cancer.

PCN9

FROM INDIRECT EVIDENCE TO DIRECT EVIDENCE: A REAL-WORLD EXAMPLE FOR THE VALUE OF INDIRECT TREATMENT COMPARISONS IN SECOND-LINE NSCLC THERAPY

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OBJECTIVES: Often new treatment options lack comparisons to treatment options which already exist on the market and which were launched several years ago. Due to such a lack of head-to-head evidence indirect treatment comparisons (ITC) are increasingly being performed. Although ITC methods are widely accepted, the results are often interpreted with caution, probably because of their lack of external validity proven by real clinical studies. **METHODS:** The first available pivotal phase-III trials for docetaxel and erlotinib in second-line non-small cell lung cancer (NSCLC) included best supportive care (BSC) as a comparator which allowed an ITC of erlotinib versus docetaxel to be performed, applying the Bucher methodology. The pemetrexed pivotal phase-III trial provided direct evidence vs docetaxel, which subsequently allowed an ITC of erlotinib vs pemetrexed to be performed. Later another phase-III trial was published comparing erlotinib vs pemetrexed, which allowed the ITC of erlotinib vs docetaxel to be re-performed. This trial and a further recently published phase-III trial directly comparing erlotinib vs docetaxel or pemetrexed, allowed the external validation of the ITC outcomes. The overall survival (OS) hazard ratios (HR) were used to produce ITC-OS HRs with 95% confidence intervals (95%CI). **RESULTS:** Comparing erlotinib versus docetaxel resulted in an ITC-OS HR of 1.25 (95%CI: 0.76-2.06, p=0.381). Using these ITC results to compare erlotinib to pemetrexed resulted in an ITC-OS HR of 1.26 (95%CI: 0.74-2.15, p=0.392). Re-performing the ITC of erlotinib versus docetaxel resulted in an ITC-OS HR of 0.95 (95%CI: 0.71-1.28, p=0.736). The head-to-head evidence validated those findings with an OS HR of 0.96 (95%CI: 0.77-1.21, p=0.916) and 0.96 (95%CI: 0.78-1.19, p=0.730), comparing erlotinib vs pemetrexed and erlotinib versus pemetrexed or docetaxel, respectively. **CONCLUSIONS:** Recently published clinical head-to-head evidence has confirmed the appropriateness and validity of ITC findings in second-line NSCLC.

PCN10

TARGETED THERAPY (TT) FOR FIRST LINE TREATMENT OF ADVANCED RENAL CELL CARCINOMA (RCC): AN INDIRECT COMPARISON META-ANALYSIS (ICMA)

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OBJECTIVES: In the past, interferon (IFN) has proven to be effective in extending the survival of patients with RCC. New TT, drugs such as Sunitinib (SU), Sorafenib (SO) and Bevacizumab (BE) have been tested against IFN. Recently, a new study was published, comparing a new TT, Pazopanib (PZ) versus placebo (PLA) but not interferon. An important question arose about the relative efficacy of PZ versus other TT and IFN, given that the control group used was not an active one in the PZ trial. When head-to-head studies are lacking; an ICMA can help solving the problem of relative efficacy. Our aim was to perform an ICMA comparing TT. **METHODS:** We performed a systematic review, searching for randomized controlled trials that compared TT against IFN or PLA, or those that compared PLA versus IFN. We conducted an indirect comparison meta-analysis that used PLA as a bridge to compare the different TT. The end point of interest was progression free survival (PFS). The results are expressed as Hazard Ratio (HR), with the corresponding confidence interval of 95% (CI). **RESULTS:** We found 8 randomized controlled trials that fit our inclusion criteria. The results of the ICMA for PFS were: PZ versus SU [HR= 1.19; CI = 0.37 to 3.85]; PZ versus IFN [HR=0.59; CI = 0.23 to 1.55]; PZ versus SO [HR=0.75; CI = 0.22 to 2.54]; PZ X BE [HR=0.83; CI=0.31 to 2.24] **CONCLUSIONS:** The results showed that PZ was superior to placebo but not to IFN. The confidence intervals obtained from the analysis were very wide precluding a definitive conclusion regarding the relative efficacy of TT, although there was a trend to confirm the superiority of SU.

PCN11

SYSTEMIC THERAPY FOR COLORECTAL CANCER: PATTERNS OF CHEMOTHERAPY AND BIOLOGIC THERAPY USE IN NATIONALLY REPRESENTATIVE CLAIMS DATABASE IN THE UNITED STATES

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OBJECTIVES: Study examined the pattern of chemotherapy and biologic therapy use by line of treatment in newly diagnosed patients with colorectal cancer (CRC). **METHODS:** Patients newly diagnosed with CRC between January 1, 2005 and June 31, 2009 and treated with systemic therapy were identified in a US-based administrative medical claims (i3 Innovus) database. Six months of patient history with no prior ICD-9 diagnosis of CRC and 1-year post-index continuous enrollment was required. Patients were followed from initial CRC diagnosis to death, disenrollment, or June 31, 2010. Chemotherapy and biologic treatments over time were analyzed to identify lines of therapy and assessed and stratified by line of therapy (1^{st}, 2^{nd}, 3^{rd} +), subgroup analysis was performed in metastatic CRC. **RESULTS:** Of 9876 patients, 45% received only 1^{st} line treatment, 35% received 1^{st} and 2^{nd} line treatment and 20% received 3^{rd} line and beyond. 60% of the study patients were identified as having metastasis either during the follow up period or at index date. The 1^{st} line, 43% received an oxaliplatin-based regimen, 5% received an irinotecan-based regimen, and 46% received 5-FU alone. 2^{nd} and 3^{rd} line settings percentages of patients treated with irinotecan-based regimens increased from 18% to 43%, respectively, use of oxaliplatin-based regimens dropped from 42% to 22%, respectively. The proportion of subjects who used bevacizumab doubled from 1^{st} to 3^{rd} line regimen. Overall, use of cetuximab and panitumumab increased from 2% in the 1st line to 7%, and 23%, respectively in the 2^{nd} and 3^{rd} + lines of treatment. **CONCLUSIONS:** Despite treatment guidelines, a large proportion of patients received 5-FU monotherapy and capecitabine as 1^{st} line treatment even for metasteses. The use of biologics in the first line was present with use in later lines. The use of EGFR inhibitors increased in the later lines of treatment after FOLFOX and FOLFIRI with or without bevacizumab.

PCN12

SURVIVAL PATTERNS BY LINE OF TREATMENT OF STAGE IV COLORECTAL (CRC) PATIENTS FROM LOCAL ONCOLOGY PRACTICE IN THE UNITED STATES

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OBJECTIVES: Stage IV CRC patients have varying survival results from multiple lines of treatment. The objective of this study was to evaluate in a real world context, the impact of adding a third line of chemotherapy to a stage IV CRC population. **METHODS:** The Georgia Cancer Specialist database (2005-2011) was used. Patients with stage IV colon or rectal cancer and treated with chemotherapy were followed from initial CRC diagnosis until death, study end or lost to follow-up. Patients were stratified into lines and type of protocol for treatments. Kaplan-Meier curves were used to compare the overall survival results between lines of therapy. **RESULTS:** There were 335 patients with confirmed stage IV CRC of which 35% received one protocol, 27% two protocols, and 38% received three or more protocols. The most common first line agents consisted of FOLFOX with or without bevacizumab or FOLFIRI with or without bevacizumab. Some single agent 5FU or 5FU with bevacizumab was observed in first line. The most common second agents were the FOLFOX or FOLFIRI not given in first line. However single agent capecitabine, cetuximab and bevacizumab were observed. In third line similar single agents but more panitumumab and capecitabine combinations were observed. Of those treated with second line (45) and three or more lines (75). The median survival was no different between the patients that received second line and those that went on to a third line (Log-Rank P=0.1249). **CONCLUSIONS:** The addition of adding a third line to a stage IV population that already received a second line failed show an association to increase survival. The benefit of adding a third line may benefit some patients and the particular combination of therapy needs to be explored in future studies.

PCN13

COST-EFFECTIVENESS ANALYSIS OF NILOTINIB VERSUS DASATINIB IN PATIENTS WITH IMATINIB-RESISTANT OR IMATINIB-INTOLERANT CHRONIC MYELOID LEUKEMIA (CML)

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OBJECTIVES: To compare the economic impact from US societal perspective of Nilotinib and Dasatinib as second-line therapies in treatment of CML patients with Imatinib resistance or intolerance by conducting a cost-effectiveness analysis. **METHODS:** A Markov simulation model was developed to estimate quality adjusted life years (QALYs) and expected costs using data from head-to-head comparative clinical trials. Costs in the model included medication cost, hospitalization cost, physician fee, laboratory test fee, adverse events cost, and value of waiting time and were obtained from published literature and government and organization websites. All costs were adjusted to 2011 US dollars. The treatment pattern was assumed to be 800mg/day for Nilotinib, or 100mg/day for Dasatinib in the chronic phase and 140mg/day in the advanced phase. Treatment was evaluated up to progression of the disease, best supportive care and up to death, operating 80 cycles of 3 months. Switching from one product to the other due to severe adverse events was also considered. Sensitivity analyses were performed to test the robustness of the results. **RESULTS:** In the base case analysis, the total cost for treatment with Nilotinib was $150,966, and Dasatinib was $126,672. Patients treated with Nilotinib gained 0.57 more life years, or 0.49 more QALYs, compared with Dasatinib. The incremental cost-effectiveness ratio (ICER) for Nilotinib therapy was $49,467/

QALY, which indicated that Nilotinib is an advantageous treatment for CML patients in regards to treatment efficacy and cost effectiveness. One-way sensitivity analyses indicated the results to be robust. **CONCLUSIONS:** Based on a willingness-to-pay threshold of $120-$150,000/QALY, Nilotinib treatment in CML patients who were resistant or intolerant to Imatinib is a cost-effective treatment. The results, however, may be less applicable to high-risk patients, the elderly, children and those eligible for bone marrow transplantation.

PCN14

SYSTEMATIC REVIEW OF CLINICAL EFFICACY AND SAFETY OUTCOMES OF ANTI-VEGF THERAPIES FOR METASTATIC COLORECTAL CANCER

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OBJECTIVES: Anti-angiogenic therapy has become an integral component of treatment for metastatic colorectal cancer patients. During last 10 years several studies were conducted to test the safety and efficacy of anti-angiogenic therapies in mCRC patients. This study reviewed the results of randomized controlled trials published in peer-reviewed journals. **METHODS:** We searched the MEDLINE, and abstracts from ECCO, ESMO and ASCO until May 2011. Studies were selected for randomized controlled trials on targeted anti-angiogenic drugs in mCRC. Primary endpoints reviewed were progression-free (PFS) and overall survival (OS). Response rates, toxicity and secondary resectability were secondary endpoints. Aggregated data were further analyzed to understand comparative safety and efficacy. **RESULTS:** Until May 2011, eligible mCRC randomized clinical trials for this review were available for bevacizumab (5 trials including 3101 patients) and vatalanib (2 trial including 2033 patients). Overall, anti-angiogensis therapy for mCRC shows significant OS and PFS benefit versus comparators. The median OS and PFS benefit for regimens containing Bevacizumab were 3 and 3.15 months, versus background chemotherapy. The median OS and PFS benefit for vatalanib containing regimens were statistically insignificant versus background chemotherapy. **CONCLUSIONS:** Anti-angiogensis therapy with Bevacizumab for mCRC shows significant OS and PFS benefit versus comparators.

PCN15

A LONGITUDINAL REVIEW OF TREATMENT PATTERNS IN PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) FROM COMMUNITY PRACTICE IN THE UNITED STATES

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OBJECTIVES: The main objective of this study was to analyze the treatment patterns in patients with advanced NSCLC treatment in a regional community setting: The Georgia Cancer Specialists Network. **METHODS:** Patients were included in the study if they were newly diagnosed with NSCLC as of the first practice visit and diagnosed with stage III or stage IV disease between January 1, 2005 and June 2010. Patients treated with chemotherapy were followed from initial NSCLC diagnosis until death, end of study period or lost to follow up. The network's Electronic Medical Record (EMR) was used to identify chemotherapy agents and sequencing of therapy. **RESULTS:** A total of 291 patients were identified with advanced NSCLC (Stage IIIB or IV). Patients ranged in the age of 40 to 85 years with 125 females and 166 males. Of the 291 patients who received first line therapy, 122 (41.9%) were treated with Carboplatin/Paclitaxel, 45 (15.5%) with Carboplatin/Paclitaxel/Bevacizumab, 24 (8.2%) with Paclitaxel and 19 (6.5%) with Bevacizumab. Of the 125 patients who received second line therapy, 52(17.9%) were treated with Pemetrexed, 13 (4.5%) with Docetaxel and 8(2.7%) with Carboplatin/Gemcitabine. The most common therapies used in the 40 patients who received third line were Pemetrexed with 11 patients (3.8%), Docetaxel with 10 patients (3.4%), Gemcitabine with 4 patients (1.4%) and Vinorelbine with 3 patients (1%). **CONCLUSIONS:** Of these patients with advanced NSCLC, 13.7% received third line therapy after previous treatment with first and second line therapies. The majority of the agents prescribed follow NCCN guidelines. In the third line the wide variation suggests a lack of standard of care. Additional rigorous clinical effectiveness trials of drugs in third line treatment are warranted to understand the benefit in NSCLC patients.

PCN16

DESIGN AND RATIONALE OF THE MULTIPLE MYELOMA PREAMBLE STUDY: A PROSPECTIVE, NON-INTERVENTIONAL, MULTI-CENTER COHORT STUDY

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BACKGROUND: Multiple myeloma (MM) is a B cell malignancy, of fully differentiated plasma cells, and is the second most prevalent hematological malignancy (10%) after non-Hodgkin's lymphoma. Despite recent advances in the treatment options for patients with MM, it remains incurable and the vast majority of patients will relapse or become refractory to treatment. To date there is little information on real world treatment outcomes for many of existing regimens. **OBJECTIVES:** The objective of this multi-center observational study is to assess treatment outcomes of patients with relapsed or refractory MM receiving either single or combination novel therapies in real-world clinical practice. **METHODS:** This is a prospective, non-interventional, cohort study that includes patients with relapsed or refractory MM who will receive treatment for MM between 2012 and 2018 in North America and Europe. In order to reflect real-world clinical practice patterns, patients currently enrolled in clinical trials are not eligible for this study. Patients will be followed for up to three years, until death, enrollment in an investigational trial, or withdrawal of consent, whichever comes first. The primary endpoints of this real world study, include disease progression/response, progression-free survival (PFS), overall survival (OS), secondary malignancy, and occurrence of adverse events. Data on patient demographics, clinical characteristics, treatment patterns, health care resources utilization, and patient-reported outcomes (e.g., EQ-5D) will also be collected by using electronic case report throughout the study. The potential association between PFS and OS in this patient population will be also assessed. The anticipated study population across multiple geographic regions is approximately 1000 patients. **RESULTS:** Findings from this prospective, non-interventional, multiregional study will contribute to the knowledge of treatment patterns for relapsed or refractory MM in real-world clinical practice.

PCN17

CHEMOTHERAPY TREATMENT AND IMPACT OF SECOND LINE CHEMOTHERAPY ON OVERALL SURVIVAL (OS) IN METASTATIC CASTRATE RESISTANT PROSTATE CANCER (CRPC) IN SOUTHEASTERN ONCOLOGY COMMUNITY PRACTICE

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OBJECTIVES: Prostate cancer represents the 2nd most common cause of cancer mortality[1]. Clinical studies showed that chemotherapy (CT) had survival benefits for Metastatic CRPC[2-6]. This study described 1st-line and 2nd-line CT and investigated OS benefits of 2nd line CT using a real-world data. **METHODS:** The Georgia Cancer Specialist Database containing CT, medical and pharmacy information, and lab results for patients (PTs) with cancer (2005-2011) was used. PTs greater than 18 years old with initial stage IV CRPC who received one type CT protocol (PL), as first-line group, and two types of PLs, as second-line group, were followed from the first administration of CT (index date, ID) to the earlier of death or loss to follow-up. CT use was described. Kaplan-Meier survival curve was compared between first-line and second-line groups using log-rank test. The impact of second-line CT on OS was further examined using multivariate Cox model with adjustment of PTs' baseline age, race, Charlson Comorbidity Index (CCI), bisphosphonate use, and ECOG performance scores. **RESULTS:** The study included 124 PTs, with 86 (69.4%) as first-line PTs, range in age from 18-90 (median 74 years of age), 52.4% of race White, 32.3% African American, and 15.3% other or unknown race, average weight was 185LB (ranging 100-365LB), average baseline PSA 731 ng/ml (ranging 0.05-21,743ng/ml), 107(86.3%) PTs with one or more CCI comorbid conditions, 10 (8.1%) PTs with ECOG score as 3 or 4. 96 (77.4%). Docetaxel was used as first-line CT. Other first-line CT drugs were: Denosumab, vinorelbine, sipuleucel-T,mitoxantrone/Prednisone, and Cisplatin. Second-line CT drugs were: denosumab, Novantrone/Prednisone, Cabazitaxel, and Carboplatin. Median survival was 17 months for all, 14 and 19 months for first-line and second-line PTs, respectively (P=0.0654). Multivariate COX model found a higher survival for second-line PTs (HR=0.361, P=0.010). **CONCLUSIONS:** This study suggested that second-line CT was associated with prolonged OS in metastatic CRPC.

PCN18

ASSESSING THE CLINICAL AND ECONOMIC BURDEN OF VETERAN BREAST CANCER PATIENTS IN THE UNITED STATES

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OBJECTIVES: To assess the clinical and economic burden of breast cancer patients in the US veteran population. **METHODS:** A retrospective study of patients diagnosed with breast cancer between October 1, 2005 and September 30, 2010 was conducted using the Veterans Health Affairs Medical SAS Datasets. Health care resource utilization and costs were assessed in the 12-month follow-up period. Patients' demographic, clinical and discharge statuses were compared using Chi-square testing and standardized differences. Mortality and survival rates were calculated using the Kaplan and Meier method and the PROC LIFETEST procedure. **RESULTS:** In patients identified with breast cancer (n=11,719), the total mortality rates in the 12-month follow-up period were 17.04% (n=1,993), with 26.07% (n=1,192) for patients age 65 and over, 10.64% for age 40 to 64, and 20.22% (n=90) for patients under age 39. The medications most commonly prescribed 1 year after breast cancer diagnosis were sodium chloride (2.43%), anastrozole (1.61%), tamoxifen (1.23%), dextrose (1.15%) and hydrochlorothiazide (1.07%). The most commonly prescribed laboratory tests were for glucose quant (3.99%), sodium (3.88%), potassium (3.81%), creatinine (3.75%), and chloride (3.73%). The percentage of patients who had follow-up inpatient visits was 19.00%, which translated into $22,220 in inpatient costs per patient, while the percentage of patients who had follow-up emergency room (ER) visits was 18.79%, which translated into $140.53 ER costs per patient. **CONCLUSIONS:** The risk of developing breast cancer increases with age. The mortality rate is relatively low for US veteran breast cancer patients between the ages of 40 and 64, but more than doubles for patients over age 65.